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December 4, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

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Re: Docket No. 00P-1499/CP1

Subject: Lotronex® is a valuable medication and should remain available as an approved agent for women with diarrhea-predominant irritable bowel syndrome.

Dear Sir or Madame:

I would like to provide comment about the value of Lotronex® (alosetron). GlaxoWellcome, Inc. should be lauded for developing and marketing this amazing medication. It has been a miracle drug for me. I find it inexcusable and outrageous that the FDA has forced GlaxoWellcome to voluntarily remove the drug from all global markets. I am devastated that I will longer be able to have access to Lotronex®.

What I cannot understand is why Viagra® is still approved for erectile dysfunction after there have been at least 130 reports of death associated with its use. Please explain this to me.

Four years ago I had a total colectomy as a therapeutic treatment for an atonic bowel condition. Until the availability of Lotronex I was a prisoner in the bathroom; requiring assess to the toilet from 10 to 25 times a day. I had tried every available antidiarrheal (Lomotil® and Imodium®) without any relief. Questran® was also prescribed for the diarrhea; it produced little if any effect. The frequent episodes of diarrhea interfered with both my personal life and professional career as a clinical toxicologist.

When Lotronex® was approved in February 2000, my gastroenterologist and I discussed whether Lotronex® might be a viable option for me despite the fact that the drug was only approved for women with diarrhea-predominant IBS. My physician and I compared the drugs potential benefits and risks and agreed that I might benefit from the drug's powerful antimotility effect. After taking two doses of Lotronex®, I noticed a tremendous improvement in bowel urgency and stool consistency and spent considerably less time in the bathroom.

I have been taking Lotronex® for eight months and have also noticed that I am able to tolerate foods that at an earlier time produced severe indigestion. I also feel less bloating and fullness after eating. I can sit through a meal now without running to the bathroom. I have also managed to gain 9 pounds; this is a good thing since I am 5'6" and weighed 100 pounds before taking Lotronex®. I feel much better about eating out at restaurants.

Lotronex® has made a tremendous improvement in the quality of my life. Dr. Sydney Wolfe (Public Citizen), who has petitioned the FDA to take Lotronex® off the market does not represent my interests. Dr. Wolfe has no ideal how much Lotronex® has improved my life and should avoid writing about what he

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has little knowledge of. Dr. Wolfe also authors a book "Good Drugs, Bad Drugs" which he sells on his web site. In his book, Dr. Wolfe also lists what he claims to be are the worst US physicians. I assume that he mentions himself as one of the worst physicians; it appears that he has not practiced clinical medicine since 1972. I am appalled that the FDA would listen to a man who boasts medical ignorance and whose anti-drug campaign is virtually self-serving.

Novel medications are approved via submission of data generated from large multicenter, double-blinded, placebo controlled studies. The evaluated drug must be efficacious, exhibiting a statistical significant difference of a validated primary endpoint over placebo effects. Adverse effects should be evaluated according to current and sound medical standards. New drug studies require an investment of $350,000 to $750,000. If drug approval is based upon evidence-based medicine, then why isn't the removal of a drug from the marketplace premised on similar science? The "prompted" withdrawal of Lotronex® by FDA is reminiscent of a witchhunt. The removal of Lotronex® does not appear to be supported by objective and unbiased review of scientific fact.

I hope that the FDA realizes the implication of its decision to force GlaxoWellcome to withdraw Lotronex®. More importantly, I urge the FDA to reexamine their request to have Lotronex® removed from the market. I am now left without any viable alternative to Lotronex® and am extremely disappointed with the FDA's decision to have Lotronex® removed from the market. My physician is unhappy about this decision also.

Respectfully yours,

[redacted]

cc: George Morrow, President & CEO, North American Operations, GlaxoWellcome, INC.
Bob Ingram, Chairman, North American Operations, GlaxoWellcome, INC.
The Honorable Bob Graham, United States Senator
The Honorable E. Clay Shaw, Jr., United States House of Representatives
The Honorable Mark Foley, United States House of Representatives